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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,384	03/30/2004	Reuben Edwin Deloach		4710

7590 10/05/2005

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EXAMINER	
DAVIS, BRIAN J	

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,384	DELOACH, REUBEN EDWIN	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/28/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed on 6/28/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered, hence, all references have been lined-through.

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A recitation of the intended utility into the preamble of a compound claim which can otherwise stand alone is not considered a further limitation on the claim. *In re Ridden*, 318, F.2d 761, 138 USPQ 112; *In re Maeder*, 337 F.2d 875, 143 USPQ 248; *Ex parte Maxey*, 177 USPQ 468 (POBA 1972); *In re Spada*, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990). This is so because a compound and its properties are inseparable. *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963).

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

With regard to rejections under 35 USC 112, first paragraph, the following factors are considered (*In re Wands* 8 USPQ 2d 1400, 1404 (CAFC 1988)): a) Breadth of claims; b) Nature of invention; c) State of the prior art; d) Level of ordinary skill in the art; e) Level of predictability in the art; f) Amount of direction and guidance provided by the inventor; g) Working examples and; h) Level of experimentation needed to make or use the invention based on the content of the disclosure.

a)The claims are breathtakingly broad: applicant claims nothing less than a silver bullet for the treatment of any and all conditions, disorders or diseases using a compound consisting of a hydrazide (claim 5). The remaining claims consist of open-ended lists of conditions, disorders, diseases and known disease-causing microorganisms (claims 6-18). Some claims are simply not believable on their face, for instance, claim 15 which is directed to the *prevention* [emphasis added] of said conditions, disorders or diseases. That is, applicant claims the prevention, inter alia, of

diseases such as Alzheimer's, Parkinson's, or indeed all diseases. Claim 16 is also not believable on its face as it is directed to, among other things, apparently even the arresting of natural aging.

The examiner respectfully reminds applicant that allegations of utility that are not believable in light of the contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. *In re Ferens*, 163 USPQ 609 (CCPA 1969); *Ex Parte Moore*, 128 USPQ 8 (Bd. Pat. App. & Int. 1960); *In re Hozumi*, 226 USPQ 353 (Comr. Dec. 1985).

b,c)The nature of the invention is determined in part by the state of the prior art. The contemporary medicinal arts, in general, teach methods of treating specific conditions, disorders or diseases with specific compounds, compositions and methods. With specific regard to the instant subject matter, the inhibition of specific proteases using specific hydrazide compounds and methods is taught (see, for instance WO 9716433, WO9848799 or WO 9966925). That is, the art does not admit the existence of a one-size-fits-all approach i.e. that of a silver bullet.

d)The level of skill in the art, in general, is considered to be relatively high.

e)The level of predictability in the art is considered to be relatively low. The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier laid the foundations of its modern practice, chemistry remains an experimental science. Neither the medicinal/biological arts nor the chemical arts upon which they are based have

advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

f,g)The amount of direction provided by the inventor is considered to be determined by the specification and the working examples. Applicant provides no working examples, laboratory or clinical data or, indeed, any evidence whatsoever, that the claimed methods are efficacious. Applicant's arguments appear to rest on armchair conjecture and back-of-the-envelope reasoning with no support of any kind from experimentation or trial. This is extraordinary. Applicant's variance with contemporary medical and laboratory standards of understanding and proof is also revealed in the specification where it is stated that "Viral altered genetic code or cancers are obvious examples [of altered or changed DNA programming], but the applicant *believes* [emphasis added] many less infectious or malignant diseases and conditions result from genetic code degradation" (page 12 paragraph 0045). Again, in light of the contemporary medical arts, this is an extraordinary assertion of blind faith unencumbered by any objective standards of understanding or proof.

h)It is not possible to make and use the instant invention without an undue level of experimentation. Applicant has not reduced the claimed instant invention to practice. The instant "invention" is a hypothesis. The specification must teach how to make and use the invention, not how to figure out for oneself how to make and use the invention. *In re Gardner*, 166 USPQ 138 (CCPA 1970).

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation "...a viral infection...", and the claim also recites "...which includes but is not limited to..." which is the narrower statement of the range/limitation. Analysis of the remaining claims is similar.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The phrase "exemplified by" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *Annals of the New York Academy of Sciences* (1959), 80, pages 555-567 (CAPLUS abstract). The instant compounds are well known in the chemical arts. The above reference, for instance, teaches RN= 3038-67-3. Indeed, applicant makes clear in the specification that the instant compounds are not at all novel: "The field of endeavor to which this invention pertains is hydrazide substrate drugs *as used in prior art applications* [emphasis added]..." (specification page 1 paragraph 0002). See also specification page 1 paragraph 0004: "This invention provides a new use for *existing drugs* [emphasis added] of the...MAOI class...".

Claims 5 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 9848799. The reference teaches hydrazide compounds as inhibitors of proteases (page 4 line 1).

Claims 5 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99966925. The reference teaches hydrazide compounds as inhibitors of proteases (page 5 line 19).

Claim 19 is rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Claim 19 is directed to a metabolic pathway. Applicant did not invent the pathway.

Claims 20 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by applicant's own admission in the body of the claim that iproniazid, isocarboxazid and nialimide are old and well-known drugs. Claims are unpatentable where the prior art process per se of applying the chemical is the same, notwithstanding applicant's different purpose for application of the compound. *In re Kirby*, 40 USPQ 368.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
October 1, 2005